In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-289V

Filed: June 2, 2016

JESSICA L. LAUGHLIN,	*	TO BE PUBLISHED
	*	
Petitioner,	*	Special Master Hamilton-Fieldman
v.	*	
	*	Gardasil; Human Papillomavirus (HPV)
SECRETARY OF HEALTH	*	Vaccine; Statute of Limitations; Premature
AND HUMAN SERVICES,	*	Ovarian Failure (POF); Primary Ovarian
	*	Insufficiency (POI); First Symptom or
	*	Manifestation of Onset; Menstrual Cycle,
Respondent.	*	Dismissal.

Mark Krueger, Krueger & Hernandez, SC, Baraboo, WI, for Petitioner.
Lara Englund, United States Department of Justice, Washington, DC, for Respondent.

DECISION[1]

This is an action by Jessica Laughlin ("Petitioner") seeking an award under the National Vaccine Injury Compensation Program (hereinafter "Program").[2] Respondent contends that the petition was untimely filed, and as such should be dismissed. For the reasons set forth below, the undersigned concludes that the petition was untimely filed, and it is therefore hereby dismissed.

[1] Because this decision contains a reasoned explanation for the undersigned's action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (hereinafter "Vaccine Act"), provides the statutory provisions governing the Program.

I. FACTUAL BACKGROUND

Petitioner was born on April 12, 1986.[3] Pet'r's Ex. 1 at 1, ECF No. 6-2. She was administered Gardasil vaccinations on June 11, 2007; August 13, 2007; and December 18, 2007. Pet'r's Ex. 3 at 12-13, 17, ECF No. 6-4.

At a gynecological visit on January 3, 2005, when she was 18 years old, Petitioner had "no GYN complaints." Pet'r's Ex. 3 at 1. She reported that her menses began at age 13, and that they had been occurring "monthly" ever since. *Id*. No developmental abnormalities were noted. *Id*. Petitioner took oral contraceptive pills "on and off" between January 2005 and November 2007. Resp't's Ex. A at 2.[4]

On November 19, 2007, when Petitioner was 21 years old, she was seen by her primary care physician for treatment of acne, which she reported developing after starting Ortho-TriCyclen Lo (a contraceptive). Pet'r's Ex. 3 at 14. She thereafter discontinued use of her contraceptive to prevent further acne, and was started on benzaclin for the acne. *Id*. In December 2007, Petitioner had an abnormal pap smear, and in January 2008, she had a colposcopy[5] that was positive for HPV. Pet'r's Ex. 3 at 29.

Petitioner's medical history remained unremarkable until the cessation of her menses at approximately age 22. Pet'r's Ex. 3 at 33. On September 9, 2008, she reported to her primary care physician that she had "no regular [menstrual] cycle since [colposcopy] and HPV vaccine." *Id.* Her treating physician noted that "[s]he is not on [oral contraceptive pills], denies associated symptoms. [Last Menstrual Period] 7/08 irreg." *Id*. When she followed up with her gynecologist on October 9, 2008, she reported her belief that the Gardasil vaccine and/or the colposcopy she underwent in 2007 and 2008 had caused her irregular menstruation. *Id*. at 37; *accord* Pet'r's Ex. 5 at 1, ECF No. 7-2 (documenting Petitioner's affidavit, in which she states, "My menstrual cycle throughout 2008 was irregular/ light."). She reported that "[s]ince her colposcopy, she is having the period [sic] about every 3 months and she will flow for 2 days, it has been very light and she has had no cramps." Pet'r's Ex. 3 at 37. Petitioner refused a pelvic examination, and was prescribed the contraceptive "Yaz." *Id*.

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[3] Petitioner's birth certificate identifies her full name at birth as "Jessica Lee Ann." Pet'r's Ex. 1 at 1.

[4] Citations to the electronic docket are not provided for exhibits filed via compact disc.

[5] A colposcopy is an examination of the cervix and vagina. Colposcopy, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*").

After her October 2008 treatment, there is a gap in her medical records of almost two years.[6] At her next documented appointment, which took place on June 10, 2010, Petitioner reported to her gynecologist that after menarche[7] at age 13, she had regular menses until "about 2 years ago," when she "got on the [oral contraceptives] and then stopped and would not have a cycle, she also admits she has gained about 20 pounds for the past 2 years. She is worried she does not have a cycle."[8] Pet'r's Ex. 2 at 1, ECF No. 6-3. She reported that while she was menstruating, the average length of her periods was five days. *Id*. She was noted to have normal vaginal rugae during her pelvic examination. *Id*. Her gynecologist ultimately concluded that "she may have PCo," but did not order relevant follow-up tests, other than a TSH test, which was normal. *Id*. at 1-3.

On February 10, 2012, Petitioner again reported to her gynecologist that she had not had a menstrual cycle in three years, Pet'r's Ex. 3 at 40, although her gynecologist's note from the same date reflects "amenhorrhea for the past one and half years." Pet'r's Ex. 3 at 41. On February 16, 2012, her gynecologist diagnosed Petitioner with primary ovarian insufficiency ("POI")[9] based upon a hormonal assessment. Pet'r's Ex. 3 at 43. Two months of FSH testing, in February and March 2012, placed her in the post-menopausal range. *Id*.

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[6] Petitioner states that the gaps in her medical history between October 9, 2008 and June 10, 2010, and between June 21, 2010 and February 10, 2012, are attributable to the fact that she did not have health insurance during these times. *See* Pet'r's Ex. 6, Petitioner's Supplemental Affidavit, at 1, ECF No. 9-2.

[7] Menarche is "the establishment or beginning of menstruation." Menarche, *Dorland's Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter "*Dorland's*"). Menstruation is "the cyclic, physiologic discharge through the vagina of blood and mucosal tissues from the nonpregnant uterus; it is under hormonal control and normally recurs, usually at approximately four-week intervals, in the absence of pregnancy during the reproductive period (puberty through menopause) of the female of the human." Menstruation, *Dorland's*.

[8] It is unclear to the undersigned whether this note reflects that Petitioner's menstrual cycles were absent or merely irregular.

[9] Although the parties and the undersigned initially used the term, "premature ovarian failure" or "POF" to define Petitioner's injury— it became clear from the literature filed by the experts that POI "is the preferred term for the condition that was previously referred to as [POF]. . . . The condition is considered to be present when a woman who is less than 40 years old has had amenorrhea for 4 months or more, with two serum FSH levels (obtained at least 1 month apart) in the menopausal range." *See* Pet'r's Ex. 15, Tab 1 at 1, *Culligan v. Sec'y of HHS*, No. 14-318V, ECF No. 53-2 (Lawrence Nelson, *Primary Ovarian Insufficiency*, 360 New Eng. J. Med. 606, 606 (2009)) (hereinafter "Nelson" with pincites to Petitioner's pagination); *see also* Resp't's Ex. A.29, *Culligan,* ECF No. 67-1 (also providing Nelson). Therefore, the undersigned will refer to the condition as POI.

At another visit with her primary care physician on April 24, 2012, she reported that she had been amenorrheic for the last three years. Pet'r's Ex. 3 at 45. She reported that "[t]wo months prior to her ameorrhea she was taking Yaz to regulate her periods, but since after stopping the Yaz [sic], she never resumed her period." *Id*. During a visit to an endocrinologist in June of 2012, Petitioner again reported that she had "a history of amenhorrhea since May 2009," prior to which she had menstruated regularly after menarche. *Id*. at 47.

II. PROCEDURAL BACKGROUND

On April 25, 2013, Petitioner filed the present action alleging that the Human Papillomavirus vaccinations ("Gardasil" or "HPV" vaccines) administered to her on June 11, August 13, and December 18, 2007 caused her to suffer from POI. Pet., ECF No. 1.

This case was identified for inclusion with other POI cases in an "omnibus proceeding" established to address the question of what constitutes the first symptom or manifestation of POI.[10] *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*, ECF No. 23. The answer to this question is integral to the undersigned's determination of whether each petitioner had filed her claim within the statute of limitations. *See* 42 U.S.C. § 300aa-16(a)(2) (2012) (requiring that petitions be filed prior to "the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury").

The lead case in the proceeding was *Culligan.*[11] In *Culligan*, Respondent opposed entitlement to compensation because the first symptom of the petitioner's POI was oligomenorrhea,[12] which she had experienced more than three years prior to the filing of her claim, making it untimely under 42 U.S.C. § 300aa-16(a)(2). *See* Resp't's Rule 4(c) Report at 3-4, *Culligan*, ECF No. 20.

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[10] Before it was transferred to the undersigned and included in the omnibus proceeding, the instant case had been pending approximately a year, and several expert reports concerning onset, addressing only the facts of this case, had been filed. Those reports and their cited literature have been considered by the undersigned in addition to evidence submitted in the omnibus proceeding.

[11] Once *Culligan* had been designated as the lead case, all of the filings for the onset proceedings were completed in the *Culligan* case, and not in the trailing cases. This section of the procedural history is therefore derived from the *Culligan* case. Citations to the *Culligan* record are so noted.

[12] Oligomenorrhea is defined as "menstrual flow happening less often than normal, defined as at intervals of 35 days to 6 months; called also *infrequent menstruation*." Oligomenorrhea, *Dorland's*.

At a *Culligan* status conference held on September 23, 2014, the undersigned discussed with the parties the necessity of establishing the date that the statute of limitations began to run in *Culligan* and other cases alleging an injury of POI caused by Gardasil in order to assess the timeliness of the claims. *See* Scheduling Order (Sept. 25, 2014) at 1, *Culligan*, ECF No. 22. The undersigned directed petitioner's counsel in *Culligan*, Mark Krueger, who is also counsel in the instant case, to begin the process of identifying other POI claimants for inclusion in an omnibus proceeding focused on the question of timeliness.[13] *Id*.

On October 1, 2014, Mr. Krueger filed a status report in which he identified eight POI cases[14] to be included in the undersigned's assessment of timeliness. *See* Pet'r's Status Report (Oct. 1, 2014), *Culligan*. Petitioner subsequently named *Culligan* as the "test case" for timeliness. *See* Pet'r's Status Report (Nov. 5, 2014) at 1, ECF No. 25.

Another status conference was held on November 20, 2014, during which the parties agreed that "in all pending [POI] cases . . . an expert hearing [would] be held to address the question of what constitutes 'the first symptom or manifestation of [POI] onset recognized as such by the medical profession at large.'" Scheduling Order (Nov. 24, 2014) at 1, *Culligan*, ECF No. 26 (citing *Cloer v. Sec'y of HHS*, 654 F.3d 1322, 1340 (Fed. Cir. 2011) (en banc)). The undersigned explained that a timeliness determination would be made on the basis of the evidence presented at the *Culligan* hearing; similar hearings would *not* be conducted in the other POI cases, all of which would trail *Culligan* for purposes of timeliness determinations. *Id*. The undersigned also added four additional POI cases[15] to the list of cases set to trail *Culligan*. *Id*. The undersigned also ordered that all parties seeking to be joined in the omnibus proceeding consent to share their medical records, *see* Scheduling Order (Nov. 24, 2014) at 2, *Culligan*, and all parties later obliged.

The parties and the undersigned proceeded to identify questions for the experts (to be researched and answered before the hearing) regarding the nature and timing of the first symptom or manifestation of onset of POI in the aforementioned cases. *See, e.g.*, Order (Feb. 18, 2015) at 1, *Culligan*, ECF No. 37; Scheduling Order (Jan. 30, 2015) at 1, *Culligan*, ECF No.

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[13] Mr. Krueger is counsel for all but one of the petitioners in the omnibus proceeding.

[14] Other than the instant case, Petitioner identified *Culligan*; *Alexander v. Sec'y of HHS*, 14-868V; *Tilley v. Sec'y of HHS*, 14-818V; *Fishkis v. Sec'y of HHS*, 14-527V; *Lee v. Sec'y of HHS*, 14-258V; *Meghan McSherry v. Sec'y of HHS*, 14-153V; *Lydia McSherry v. Sec'y of HHS*, 14-154V. Pet'r's Status Report (Oct. 1, 2014) at 1, *Culligan*, ECF No. 23.

[15] The four added cases were *Chenowith v. Sec'y of HHS*, 14-996V; *Bello v. Sec'y of HHS*, 13-349V; *Olivia Meylor v. Sec'y of HHS*, 10-771V; *Madelyne Meylor v. Sec'y of HHS*, 10-770V. *Id.* The petitioners in these cases were all represented by Mr. Krueger.

36; Pet'r's Status Report (Dec. 29, 2014) at 1, *Culligan*, ECF No. 31; Scheduling Order (Nov. 24, 2014) at 2, *Culligan*; Resp't's Status Report (Oct. 28, 2014) at 1, *Culligan,* ECF No. 24. The parties and their experts ultimately agreed that, except in *Culligan*, in which the entire medical record would be considered by the experts, the experts would "offer opinions regarding the onset issues in the trailing cases by considering the facts of those cases as hypotheticals." Joint Status Report (Jan. 20, 2015) at 1, *Culligan*, ECF No. 33. To facilitate this process, Petitioner filed summaries of the facts of all twelve POI cases. *See* Pet'r's Ex. 9, *Culligan*, ECF No. 34-2.[16] Except in *Culligan*, the experts were to rely on the factual summaries, in lieu of the medical records themselves, to articulate their opinions regarding timeliness. *See* Joint Status Report (Jan. 20, 2015) at 1, *Culligan*.

At a status conference held on January 28, 2015, the undersigned set deadlines for the parties' expert reports regarding timeliness. *See* Order (Jan. 30, 2015) at 2, *Culligan*. The experts were directed to address all of the identified timeliness questions separately, "on a question-by-question basis." *Id*. at 1.

On February 19 and March 3, 2015, three additional cases,[17] all filed by Mr. Krueger, were added to the list of POI trailing cases. *See* Scheduling Order (Mar. 3, 2015) at 1, *Culligan*, ECF No. 45; Scheduling Order (Feb. 19, 2015) at 1, *Culligan*, ECF No. 38. Mr. Krueger subsequently filed factual summaries of the three new cases. *See* Pet'r's Exs. 10, 11, 12, *Culligan*, ECF Nos. 40-2, 41-2, 44-2.

On March 12, March 13, and April 29, 2015, Petitioner filed expert reports and supporting medical literature, all of which were purportedly limited to the issue of timeliness. *See* Pet'r's Ex. 13, *Culligan*, ECF Nos. 47-2 to 51-6; Pet'r's Ex. 15, *Culligan*, ECF Nos. 53-1 to 54-3; Pet'r's Ex. 17, *Culligan*.[18] The expert reports were authored by Dr. Felice Gersh and Dr. Orit Pinhas-Hamiel. *See* Pet'r's Ex. 13, Tab 1, *Culligan*; Pet'r's Ex. 15, Tab 1, *Culligan*. The reports filed by Drs. Gersh and Hamiel reflected that they had reviewed the medical records underlying all of the POI cases. *See* Pet'r's Ex. 13, Tab 1 at 12-13, *Culligan*; Pet'r's Ex. 15, Tab 1 at 17, *Culligan*.

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[16] A factual summary for another trailing POF case–*Smith*, 14-1107V –was also filed in *Culligan*. *See* Order (Feb. 23, 2015) at attachment 1-2, *Culligan*, ECF No. 39; *see also* Order (Jan. 30, 2015) at 1-2, *Culligan*, ECF No. 36; Order (Jan. 26, 2015), *Culligan*, ECF No. 35. The petitioner in *Smith* was represented by different counsel.

[17] The cases were *Brayboy v. Sec'y of HHS*, 15-183V; *Garner v. Sec'y of HHS*, 15-143V; and *Vakalis v. Sec'y of HHS*, 15-134V.

[18] Petitioner filed Exhibit 17 via compact disc. *See* Notice of Intent to File on Compact Disc (Apr. 29, 2015), *Culligan*, ECF No. 56.

The undersigned convened a status conference on April 1, 2015, after having reviewed Petitioner's expert reports. *See* Scheduling Order (Apr. 2, 2015) at 1, *Culligan,* ECF No. 55. The undersigned noted that, "notwithstanding the fact that Petitioner's onset experts have now reviewed the medical records associated with every [POI] case, Respondent's onset expert(s) will review only the cases' factual summaries, the *Culligan* record, and Respondent's list of hypothetical questions." *Id*. Also, having expressed some concern about the extent to which Petitioner's expert reports reflected an understanding of the relevant question regarding timeliness, the undersigned reiterated the following:

> [T]he relevant date, for purposes of assessing onset under *Cloer*, is *not* the first point in time at which a definitive diagnosis could have been made; rather, it is the time at which the first symptom or manifestation of the allegedly vaccine-caused injury occurred. The onset experts must make this assessment with the benefit of hindsight, rather than placing themselves in the shoes of the treating, diagnosing physicians. The parties are directed to address this issue as specifically as possible in their pre-hearing briefs.

Id. (internal citations omitted).

Respondent then filed an expert report regarding timeliness, as well as relevant medical literature, on May 8, May 28, and June 1, 2015. Resp't's Ex. A to A.32, *Culligan,* ECF Nos. 57-1 to 59-6, 63-1 to 63-3, 66-1 to 67-4. Respondent's expert report was authored by Dr. David Frankfurter. Resp't's Ex. A at 6, *Culligan*.

At a status conference held on May 14, 2015, Respondent confirmed that, in preparing his expert report, Dr. Frankfurter had reviewed only the factual summaries submitted by Petitioner (and the medical record from *Culligan*). *See* Order (May 15, 2015) at 1, *Culligan,* ECF No. 61. Mr. Krueger agreed that, notwithstanding the fact that his experts had reviewed all of the medical records in all of the POI cases, "his experts would be referring to the factual summaries rather than to the medical records themselves" at the timeliness hearing. *Id*.

The parties filed their pre-hearing briefs simultaneously on June 1, 2015, *see* Pet'r's Prehearing Submissions, *Culligan,* ECF No. 65; Resp't's Prehearing Submissions, *Culligan,* ECF No. 69; and the hearing took place on June 16 and 17, 2015, *see* Minute Entry (June 18, 2015), *Culligan*. Petitioner's experts, Drs. Gersh and Hamiel, and Respondent's expert, Dr. Frankfurter, testified. Tr. at 4, 255, *Culligan,* ECF Nos. 81, 83.

On July 1, 2015, the undersigned issued an order identifying nine POI cases[19] "as presumptively precluded under the applicable statute of limitations." Order (July 1, 2015) at 1, *Culligan,* ECF No. 79. *Culligan* was included among the presumptively precluded cases. *Id*. The undersigned also identified six cases[20] that appeared to have been timely filed. *Id*. Having apprised the parties of these preliminary conclusions, the undersigned granted them additional time to file status reports identifying the cases in which they intended to contest this determination, and explaining what they had identified as the first symptom or manifestation of onset in each of those cases. *Id*. at 2.

On August 28, 2015, Respondent filed a status report in which she stated that she did not intend to contest the undersigned's preliminary findings in any of the presumptively timely cases filed by Mr. Krueger. Resp't's Status Report (Aug. 28, 2015) at 1, *Culligan,* ECF No. 84. In status reports filed on September 2 and 30, 2015, Petitioner argued that all of the preliminarily precluded cases were, in fact, timely. *See* Pet'r's Status Report (Sept. 2, 2015) at 2-7, *Culligan*, ECF No. 85 (addressing *Culligan*, *Chenowith*, *Garner*, *Lee*, *Lydia McSherry*, and *Madelyne Meylor*); Pet'r's Status Report (Sept. 30, 2015) at 1-2, *Culligan,* ECF No. 87 (addressing *Fishkis*, *Meghan McSherry*, *Stone*).

At a status conference held on October 13, 2015, the undersigned "informed the parties that, for purposes of an onset determination, the [POI] cases [would] be divided [into] two groups: petitioners who never menstruated . . . and the rest of the [POI] petitioners." *See* Scheduling Order (Oct. 14, 2015) at 1, *Culligan,* ECF No. 88.

Relevant post-hearing briefing[21] concluded on January 20, 2016. *See* Pet'r's Post Hr'g Br., *Culligan,* ECF No. 91; Resp't's Post Hr'g Brs., *Culligan,* ECF No. 94; Pet'r's Post Hr'g Reply Br., *Culligan,* ECF No. 95. Petitioner's claim is now ready for a determination of the first symptom or manifestation of onset of the alleged vaccine-related injury; and, relatedly, whether the Vaccine Act's statute of limitations bars the claim.

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[19] The instant case, as well as *Culligan*, *Chenowith*, *Fishkis*, *Garner*, *Lee*, *Lydia McSherry*, *Meghan McSherry*, and *Madelyne Meylor*. Order (July 1, 2015) at 1.

[20] *Alexander*, *Bello*, *Brayboy*, *Olivia Meylor*, and *Vakalis*. *Id.* The undersigned also identified as timely *Smith*, a trailing POF case that had been filed by a different attorney. *Id.* In *Tilley*, the undersigned directed the parties to file additional briefs regarding timeliness. *Id.*

[21] Briefing addressing Petitioner's request for interim attorneys' fees is not relevant to the timeliness issue and is therefore not included in this discussion.

III. ANALYSIS

A. Applicable Legal Standard

Section 300aa-16(a)(2) of the Vaccine Act provides that, regarding

> a vaccine set forth in the Vaccine Injury Table which is administered after [October 1, 1998], if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury.

42 U.S.C. § 300aa-16(a)(2).

This statute of limitations is not triggered by the administration of the vaccine, but "begins to run on the date of occurrence of the first symptom or manifestation of onset of the vaccine-related injury for which compensation is sought." *Cloer*, 654 F.3d at 1335. "[E]ither a 'symptom' or a 'manifestation of onset' can trigger the running of the statute [of limitations], whichever is first." *Markovich v. Sec'y of HHS*, 477 F.3d 1353, 1357 (Fed. Cir. 2007).

"[I]t is the first symptom or manifestation of an alleged vaccine injury, not first date when diagnosis would be possible, that triggers the statute of limitations." *Carson ex rel. Carson v. Sec'y of HHS*, 727 F.3d 1365, 1369 (Fed. Cir. 2013), *reh'g & reh'g en banc denied*, 2013 WL 4528833 at *1. "A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the medical significance of a symptom with regard to a particular injury." *Markovich*, 477 F.3d at 1357. While the symptom of an injury must be recognized as such "by the medical profession at large," *Cloer*, 654 F.3d at 1335, even subtle symptoms that a petitioner would recognize "'only with the benefit of hindsight, after a doctor makes a definitive diagnosis of injury,'" trigger the running of the statute of limitations, whether or not the petitioner or even multiple medical providers understood their significance *at the time*. *Carson*, 727 F.3d at 1369-70 (quoting *Markovich*, 477 F.3d at 1358).[22]

[22] Petitioner argues that "POI is a latent injury" and that "the first symptom of onset, in terms of the applications [sic] of the statute of limitations, can be subtle and can precede manifestation of onset by months or even years." Pet'r's Post Hr'g. Br. at 9. This argument has been made before: the Court of Federal Claims, in *Setnes v. United States*, 57 Fed. Cl. 175 (2003), "was concerned with the very subtle symptoms attributed with autism that can be easily confused with typical child behavior, and it distinguished the terms 'symptom' and 'manifestation.'" *Markovitch*, 477 F.3d at 1357-58. The *Setnes* court's interpretation of the "first symptom or manifestation of onset" language of the statute was rejected by *Markovich*, a ruling that has since been reaffirmed by the Federal Circuit en banc in *Cloer*. 654 F.3d at 1334-1335.

There is no explicit or implied discovery rule under the Vaccine Act. *Cloer,* 654 F.3d at 1337. The date of the occurrence of the first symptom or manifestation of onset of the alleged vaccine-related injury "does not depend on when a petitioner knew or reasonably should have known anything adverse about her condition." *Id.* at 1339. Nor does it depend on when a petitioner knew or should have known of a potential connection between an injury and a vaccine. *Id.* at 1338 ("Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury."); *see Markovich*, 477 F.3d at 1358 ("Congress intended the limitation period to commence to run prior to the time a petitioner has actual knowledge that the vaccine recipient suffered from an injury that could result in a viable cause of action under the Vaccine Act." (internal quotation marks omitted)).

B. Symptoms of POI Onset, Including Criteria for Distinguishing "Symptom" from "Normal"

Primary ovarian insufficiency can begin abruptly, *see* Tr. at 69; *see also* Nelson at 2-3; but it may also develop over several years, *see* Tr. at 70, 198-99, 398; *see also* Nelson at 2-3; Pet'r's Ex. 17, Tab 50 at 2 (Paolo Beck-Peccaz & Luca Persam, *Premature Ovarian Failure*, 1 Orphanet J. Rare Diseases, at 2 (Apr. 2006)) (hereinafter "Beck-Peccaz"). Thus, a woman could have symptoms of POI for several years before actually ceasing menstruation or being diagnosed with POI. *See* Tr. at 70, 198-99, 398*; see also* Tr. at 319; Nelson at 2-3; Beck-Peccaz at 2. The experts agreed that the symptoms of primary ovarian insufficiency include menstrual irregularities, including primary and secondary amenorrhea,[23] cycle and frequency irregularity, and excessive or prolonged bleeding; delayed menarche; lack of breast development and poor growth velocity; night sweats; hot flashes; sleep disturbances; mood changes; recurring ovarian cysts; arrested puberty; and marked hirsutism. Tr. at 38, 57, 68-69, 319, 366. Most of these symptoms are not "normal" for a woman under the age of 40. Petitioner therefore does not dispute that they can constitute the "first symptom or manifestation of onset" of POI for purposes of the Act's statute of limitations, and there was little discussion of the symptoms beyond their inclusion on the list of symptoms. As to menstrual irregularities and delayed menarche, however, Petitioner and Petitioner's experts dispute that these two conditions should be considered symptoms at all, because many young women experience these conditions at the beginning of their reproductive lives, such that these conditions are considered "normal." *See,*

[23] Amenorrhea is "absence or abnormal stoppage of the menses." Amenorrhea, *Dorland's*. Primary amenorrhea is "failure of menstruation to occur at puberty." Primary Amenorrhea, *Dorland's*. Secondary amenorrhea is "cessation of menstruation after it has once been established at puberty." Secondary Amenorrhea, *Dorland's*.

e.g., Pet'r's Post Hr'g Br. at 2, 4-8; Tr. at 32, 58, 61, 72-73, 170-71; *see also* Tr. at 380 (Respondent's expert, Dr. Frankfurter, explaining that it is normal for a teenager to have irregularity, albeit within a range). As a result, Petitioner and her experts claim, menstrual irregularity only constitutes a symptom or manifestation of onset of POI when that irregularity is effectively considered secondary amenorrhea. Pet'r's Post Hr'g Br. at 4-5; Pet'r's Post Hr'g Rep. Br. at 3.

By instead finding that "normal" menstrual irregularity is a symptom for purposes of the Act's statute of limitations, Petitioner argues, the undersigned will somehow increase Petitioner's burden of proof. *See* Pet'r's Post Hr'g Reply Br. at 1-2. The undersigned does not agree. The undersigned does agree, however, that to qualify as the first symptom or manifestation of onset under the Act, a condition must be a symptom of something amiss, however subtle; it cannot be "normal": a symptom is "[a]ny morbid phenomenon *or departure from the normal* in structure, function, or sensation, experienced by the patient and indicative of disease." Symptom, *Stedman's Medical Dictionary* (28th Ed. 2013) (hereinafter "*Stedman's*") (emphasis added); *accord Markovich*, 477 F.3d at 1360 (observing that eye blinking episodes constituting first symptom of child's seizure disorder "were not normal child behavior"). In order to determine the date of the first symptom or manifestation of onset of the vaccine-related injury, therefore, a method for separating "normal" menstrual irregularities from abnormal symptoms of POI is necessary.[24]

Fortunately, medical literature provided by the parties provides a solution, both simple and elegant. *See* Resp't's Ex. A.2, ECF No. 57-4 (Comm. on Adolescent Health Care, Am. Coll. of Obstetricians & Gynecologists, *Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign*, Comm. Op. No. 349 (Nov. 2006)) (hereinafter "ACOG Opinion" or "ACOG Op."); *see also* Pet'r's Ex. 15, Tab 4. In *Cloer* and *Markovich*, the Federal Circuit directed that "the symptom or manifestation of onset must be recognized as such by the medical profession at large." *Cloer*, 654 F.3d at 1335; *Markovich*, 477 F.3d at 1360. The ACOG Opinion is an opinion from the Committee on Adolescent Healthcare at the American College of

[24] Petitioner also argues that irregular menstruation should not be considered the first symptom of POI because it "can be explained by other causes." Pet'r's Post Hr'g Reply Br. at 2-3. This argument has been repeatedly rejected by the Federal Circuit, and is equally as unpersuasive here. A symptom need not be exclusive to the particular injury alleged in order to be "the first symptom" of that injury for purposes of the Act. *See Markovich*, 477 F.3d at 1357 ("A symptom may be indicative of a variety of conditions or ailments, and it may be difficult for lay persons to appreciate the significance of a symptom with regard to a particular injury."); *see also Carson*, 727 F.3d at 1370 (holding that even where "[t]here is no question that speech delay can be indicative of several conditions, and in some circumstances may even be normal . . . it was not arbitrary and capricious for the Chief Special Master to find that the severe speech delay . . . was the first objectively recognizable symptom of autism, the alleged vaccine injury.")

Obstetricians and Gynecologists, together with the American Academy of Pediatrics, entitled "Menstruation in Girls and Adolescents: Using the Menstrual Cycle as a Vital Sign." *See* ACOG Op. It was issued in November 2006, and "Reaffirmed" in 2009. ACOG Op. at 1. The abstract of the ACOG Opinion provides:

> It is . . . important for clinicians to have an understanding of bleeding patterns in girls and adolescents, the ability to differentiate between normal and abnormal menstruation, and the skill to know how to evaluate young patients' conditions appropriately. Using the menstrual cycle as an additional vital sign adds a powerful tool to the assessment of normal development and the exclusion of serious pathologic conditions.

Id. The article goes on to discuss a number of articles and robust epidemiological studies concerning what constitutes "normal menstrual cycles in young females," including age at menarche, and "cycle length and ovulation," *id.* at 2-3; "abnormal menstrual cycles," including "prolonged interval[s]," *id.* at 3-4; and "excessive menstrual flow," *id.* at 4. The article concludes with a chart, reproduced below, that together with one difference applicable to women older than 18, provides comprehensive guidance to the "medical profession at large" about when menstrual irregularities have exceeded "normal" variation to become symptoms of a potential problem. *Id.* at 4-5. The chart is as follows:

Menstrual Conditions That May Require Evaluation

Menstrual periods that:

- Have not started within 3 years of thelarche[25]
- Have not started by 13 years of age with no signs of pubertal development[26]
- Have not started by 14 years of age with signs of hirsutism[27]

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[25] Thelarche is "the beginning of development of breasts in the female." Thelarche, *Stedman's*.

[26] Pubertal development is measured by assessing an individual's stages of puberty using the Tanner growth chart, which is "based on pubic hair growth, development of genitalia in boys, and breast development in girls." Tanner stage, *Stedman's*. For purposes of the ACOG criteria, the undersigned considers Tanner stages I (child) and II (prepubertal) as showing "no signs of pubertal development," and Tanner stags III (early pubescent) and IV (late pubescent) as showing such signs. Dr. Frankfurter testified that a young woman who has never menstruated and who has no signs of secondary sexual development by age 13 should be evaluated. Tr. at 377.

[27] Hirsutism is the "presence of excessive bodily and facial hair, usually in a male pattern, especially in women." Hirsutism, *Stedman's.*

- Have not started by 14 years of age with a history or examination suggestive of excessive exercise or eating disorder
- Have not started by 14 years of age with concerns about genital outflow tract obstruction or anomaly
- Have not started by 15 years of age[28]
- Are regular, occurring monthly, and then become markedly irregular[29]
- Occur more frequently than every 21 days or less frequently than every 45 days[30]
- Occur 90 days apart even for one cycle[31]
- Last more than 7 days
- Require frequent pad or tampon changes (soaking more than one every 1-2 hours)

Id. at 5.

Hillard reproduces this chart, accompanied with this caution:

> Failure to evaluate teens who meet the criteria cited in the [ACOG] Opinion can be a significant disservice to young women, leading to unnecessary discomfort, embarrassment, poorer quality of life, adverse self esteem, and current or future health risks such as anemia and low bone mineral density, as well as potential

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[28] At the hearing, Doctors Hamiel and Gersh opined that an adolescent who has not reached menarche by age 16 should be evaluated for primary amenorrhea. Tr. at 92, 238. Dr. Frankfurter opined that the age of evaluation should be 15 years. Tr. at 365. Both the ACOG Opinion and Dr. Hillard, author of medical literature introduced by Petitioner, acknowledge that the traditional definition of primary amenorrhea has been no menarche by age 16. ACOG Op. at 2; Pet'r's Ex. 15, Tab 4, at 5, ECF No. 53-5 (Hillard, Paula, *Menstruation in Adolescents: What Do We Know? and What Do We Do with the Information?*, 27 J. Pediatric Adolescent Gynecology 309 (2014)) (hereinafter "Hillard" with pincites to Petitioner's pagination). However, both articles note that 95-98% of females will have experienced menarche by age 15, and that delays in evaluating these young women can result in delays in detection and treatment of significant disorders, including POI. ACOG Op. at 2; Hillard at 6.

[29] At the hearing, Dr. Hamiel testified that she would recommend further evaluation of a non-adolescent woman whose cycle had been regular (21-35 days) and then became irregular (less frequent than every 35 days). Tr. at 67.

[30] For women over the age of 18, this criterion is more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3; *see also* Tr. at 39 (documenting Dr. Hamiel's testimony normal menstrual frequency for a woman in her twenties is 21-35 days). The undersigned interprets this criterion to apply to frequency over two or more cycles.

[31] At the hearing, Dr. Hamiel testified that no menstruation for 90 days is not "normal." Tr. at 79.

> metabolic and cardiovascular risks. . . . [J]ust as with other vital signs like pulse and respiration, *[menstrual cycle] values outside of statistically derived normal parameters may signal disease or derangements in normal health.*

Hillard at 8 (emphasis added).

There cannot be a better vehicle for the undersigned to use to sort out "normal" from "symptom" than one designed for that purpose by members of the medical profession themselves. Thus, the undersigned finds that for petitioners who were eighteen years old or younger at the time the condition arose, if the condition qualifies for evaluation on the ACOG chart, it constitutes a symptom for purposes of the Vaccine Act. For petitioners who were over eighteen years old at the time the condition arose, the chart also applies, except that periods that should be evaluated include those that occur more frequently than every 21 days or less frequently than every 34 days. *See* ACOG Op. at 3.[32]

Finally, as to contraceptives' impact on this analysis, Hillard specifically limited her discussion "only to bleeding on young women who are *not* taking any hormonal therapy such as birth control." Hillard at 6. All of the experts at the hearing agreed that hormonal therapy would mask POI symptoms. Tr. at 115, 161, 387-88. The ACOG Opinion recommends blood collection for screening before hormonal treatment is begun, ACOG Op. at 4, as did Doctors Hamiel, Tr. at 95-97, and Frankfurter, Tr. at 377, at the hearing; although, both experts acknowledged that such testing is often not performed before hormonal treatment is started. Tr. at 95-97, 112-13, 387-92.

Based on that information, the undersigned makes the following findings regarding how contraceptive use will inform the undersigned's findings on onset for purposes of the statute of limitations:[33]

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[32] To the extent Petitioner argues that this interpretation of the Vaccine Act's statute of limitations violates the Fifth Amendment on Equal Protection and Due Process Grounds, *see* Pet'r's Post Hr'g Br. at 11-13, the undersigned concurs with the reasoning articulated in numerous decisions to the contrary, all of which hold that the Act's statute of limitations does not violate the Constitution merely because it bars certain petitioners from bringing a claim before they knew, or even could have known, that their injuries were vaccine-related. *See, e.g.*, *Cloer v. Sec'y of HHS*, 85 Fed. Cl. 141, 150-51 (2008), *rev'd on other grounds*, 603 F.3d 1341, *aff'd en banc*, 654 F.3d 1322 (Fed. Cir. 2011); *Leuz v. Sec'y of HHS*, 63 Fed. Cl. 602, 607-12 (2005); *Wax v. Sec'y of HHS*, No. 03-2830V, 2012 WL 3867161, at *6-8 (Fed. Cl. Spec. Mstr. Aug. 7, 2012); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 647, 655-57 (S.D. Tex. 2004); *Reilly ex rel. Reilly v. Wyeth*, 876 N.E.2d 740, 753-54 (Ill. App. Ct. 2007).

[33] This decision expresses no opinion concerning the effect, if any, of contraceptive use on the question of causation in a POI case.

1. If the form of contraceptive used was non-hormonal, i.e., a copper IUD without hormones,[34] condom/diaphragm, spermicide, the ACOG criteria apply as discussed above, without changes;
2. By definition, a contraceptive is "an agent that diminishes the likelihood of or prevents conception." Contraceptive, *Dorland's*. Therefore, if the medical records show that a hormonal contraceptive was prescribed for its primary purpose, that is, for contraception, rather than as treatment for menstrual irregularities; or if the medical records are silent as to the purpose of the prescription and the contraceptive use spanned the date on which the statute of limitations would have begun to run; the statute of limitations will not preclude the claim;
3. If the medical records indicate that the hormonal contraceptive was prescribed to treat menstrual irregularities, or if menstrual irregularities were a reason for the medical visit that resulted in the prescription of the contraceptive, then the undersigned will find that the menstrual irregularities were not "normal," but resulted in treatment, and therefore constituted a symptom for purposes of the statute of limitations.

C. Application of the Onset Symptom Criteria to the Present Case

This petition was filed on April 25, 2013; in order for it to have been timely, the first symptom or manifestation of onset of Petitioner's allegedly vaccine-caused POI must have occurred no earlier than April 25, 2010.

Prior to the inclusion of the instant case in the omnibus proceeding, Petitioner filed three expert reports authored by Dr. Felice Gersh. *See* Pet'r's Exs. 8, 15, and 20, ECF Nos. 20-2, 27, 34-2. Prior to hearing, Dr. Gersh's theory was that "the first signs and symptoms of premature ovarian failure were not apparent until approximately June 2010." Pet'r's Ex. 8 at 1. According to Dr. Gersh, "when considering the timing of onset of symptoms which could be recognized as due to premature ovarian failure, as opposed to common irregular menstruation, definitive secondary amenorrhea would have to be clearly documented." *Id*. Dr. Gersh defined secondary amenorrhea as "the absence of spontaneous menstrual periods [for a period of at least 6 months] after a period of time during which menstrual cycles, regular or irregular, occurred." *Id*.

Applying this standard to Petitioner's medical records, Dr. Gersh opined that the first symptom of Petitioner's allegedly vaccine-caused POI was in approximately June 2010. *Id*. at 3; Pet'r's Ex. 15 at 7. Dr. Gersh explained that, although Petitioner reported an absence of menstrual cycle for three years preceding her gynecological visit in February of 2012, her doctor

[34] Dr. Frankfurther indicated that non-hormonal copper IUDs may affect the volume of flow but do not influence the cycle length or frequency. Tr. at 422.

documented only one and a half years of amenorrhea. Pet'r's Ex. 8 at 2. This is likely to have been because Petitioner was taking oral contraceptives for part of the three year period; the absence of menstrual cycles while on oral contraception does not "count" as secondary amenorrhea because "it has no bearing on a woman's underlying pathology." *Id*.

Moreover, Dr. Gersh opined, based on the notes of Petitioner's treating physician on June 10, 2010, that Petitioner did not have menstrual cycles after discontinuation of her oral contraception, and that this was likely attributable to recent weight gain and polycystic ovary syndrome ("PCO" or "PCOS"[35]). *Id*.; Pet'r's Ex. 2 at 1-2. Petitioner's documented acne and weight gain, along with her menstrual irregularity, "fulfill[] the diagnostic criteria needed for a diagnosis of PCOS. Pet'r's Ex. 15 at 5. In June 2010, her treating physician documented that Petitioner had "rugated vaginal mucosa," which, Dr. Gersh agreed, supports the assumption that Petitioner was still producing normal amounts of estrogen at that time. Pet'r's Ex. 8 at 2 (Dr. Gersh stating that "[l]ow estrogen levels cause vaginal atrophy and regression of vaginal rugae," and "[a]novulation due to ovarian failure results in severely reduced production of estrogen"). Because Petitioner met the criteria for PCOS but exhibited no signs of estrogen deficiency (e.g., hot flashes and vaginal atrophy) in 2008 and 2009, Dr. Gersh opined, it is logical to conclude that her symptoms during that period were attributable to PCOS rather than POI. Pet'r's Ex. 15 at 4-6. Dr. Gersh appears to acknowledge, however, that Petitioner's PCOS and POI were simultaneous processes with "blatantly overlapping symptoms," that "[i]t is virtually impossible to definitively state when the [POI] actually began," and that "it is absolutely impossible to separate out the effects on [Petitioner's] menses from the PCOS, the autoimmune thyroid disease, and the [POI]." *Id*. at 5, 7.

Respondent filed an expert report authored by Dr. David Frankfurter. Resp't's Ex. A. In his report, Dr. Frankfurter argued that the onset of Petitioner's POI occurred in January 2009. Resp't's Ex. A at 14. He notes that this assessment has been complicated by the gaps in in her medical records and by the fact that she was on and off oral contraceptives. *Id*. at 6, 9-10. However, he finds clear documentation that "she discontinued [oral contraceptives] in November 2007, [that] her cycles became irregular by June 2008, and they stopped completely by the end of 2008," Dr. Frankfurter concludes that there is a strong suggestion of onset of ovarian dysfunction by mid-2008. *Id*. at 10.

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[35] Polycystic ovary syndrome, or PCOS, "is a common endocrine system disorder among women of reproductive age" featuring "enlarged ovaries that contain small collections of fluid—called follicles—located in each ovary as seen during an ultrasound exam." Mayo Clinic Staff, Polycystic ovary syndrome: Definition, http://www.mayoclinic.org/diseases-conditions/pcos/basics/definition/con-20028841 (last visited May 9, 2016); *see* Pet'r's Ex. 13, Tab 37 at 2, *Culligan*, ECF No. 51-3 (Mohd Ashraf Ganie et al., *High prevalence of polycystic ovary syndrome characteristics in girls with euthyroid chronic lymphocytic thyroiditis: a case-control study*, 162 Eur. J. Endocrinology 1117 (2010)).

Dr. Frankfurter disagrees with Dr. Gersh regarding her diagnosis of contemporaneous PCOS. *Id.* at 11-14. He believes that Petitioner's weight gain resulted from the thyroid condition that followed her POI, not from menstrual dysfunction, and that her acne predated any ovarian dysfunction. *Id*. at 9, 14. He points out that once Petitioner's oral contraception was discontinued in November 2007, her menstruation should have resumed on a normal cycle; it would not have affected her menstruation beyond the time that it was taken. *Id*. at 10-11; *See also Culligan*, ECF No. 57-2, at 10-11 (noting that oral contraceptives mask the symptoms of POI). Finally, he argues that "the presence of rugae in a young, sexually active woman is not a reliable indicator of estrogen status;" "[i]t is known that women without ovarian function can retain a normal appearing mucosa and that women who have their ovaries removed can retain a normal maturation index (measure of estrogen's effect on the vaginal epithelium)[.]" *Id*. at 12-13.

At hearing, Dr. Frankfurter explained that PCOS is a diagnosis of exclusion, to be used only when other diagnoses that mimic it, such as POI, have been ruled out. Tr. at 325, 343. He argued that "in order to invoke th[e] diagnosis of PCOS, you need to rule out ovarian insufficiency, which is why we check an FSH." Tr. at 345. Dr. Gersh disagreed that PCOS is a diagnosis of exclusion, though she agreed that "a few" causes for a woman's ovarian dysfunction[36] should be ruled out before PCOS is diagnosed. Tr. at 228-29.

The undersigned acknowledges that the record is somewhat ambiguous with respect to the extent of Petitioner's use of oral contraceptives. However, Petitioner specifically reported to her primary care physician on September 9, 2008 – one month before her October 2008 appointment – that "[s]he [was] not on [oral contraceptive pills]," and that per last menstrual cycle had occurred in July of 2008. Pet'r's Ex. 3 at 33.

The undersigned declines to find that Petitioner's 2008 and 2009 symptoms were attributable to PCOS rather than POI. Dr. Gersh acknowledges that Petitioner's PCOS and POI were simultaneous processes with "blatently overlapping symptoms," that "[i]t is virtually impossible to definitively state when the POF actually began," and that "it is absolutely impossible to separate out the effects on [Petitioner's] menses from the PCOS, the autoimmune thyroid disease, and the [POI]." *See* Pet'r's Ex. 15 at 5, 7. In any event, "[a] symptom may be indicative of a variety of conditions or ailments. *Markovich*, 477 F.3d at 1357; *see also Carson*, 727 F.3d at 1369. It is not necessary for the undersigned to find that a symptom is exclusive to POI to find that it is *the first* symptom of POI.

[36] Dr. Gersh identified the other causes to be ruled out as Cushing syndrome, adrenal hyperplasia, and "certain thyroid dysfunctions." Tr. at 229.

Applying the ACOG standard, the undersigned finds that the first symptom of Petitioner's POI had occurred by October 9, 2008, when she reported to her gynecologist that "[s]ince her [January 2008] colposcopy, she is having the period [sic] about every 3 months and she will flow for 2 days." Pet'r's Ex. 3 at 37. ACOG defines, as a menstrual condition that requires evaluation in a woman over the age of 18, menstrual cycles that occur more frequently than every 21 days or less frequently than every 35 days. *See* ACOG Op. at 3. Because Petitioner was having menstrual cycles "about every 3 months" for an eight-month period, that ACOG criterion for irregularity had been met. In addition, because Petitioner's menstrual cycle had been regular, "monthly," for a number of years, and then became irregular, "about every 3 months," it also satisfies the ACOG criterion for evaluation of periods that were regular, and then "[became] markedly irregular." *Id*.

The undersigned finds that the first symptom or manifestation of onset of Petitioner's POI occurred no later than October 2008. Accordingly, her claim is time-barred.

IV. CONCLUSION

Based on the foregoing analysis, the undersigned finds that the first symptom of Petitioner's injury was no later than October 2008. Because that date precedes the statute of limitations deadline by over a year, the undersigned concludes that Petitioner's claim is time-barred. Her petition therefore must be, and is hereby, **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.[37]

/s/ Lisa D. Hamilton-Fieldman
Lisa D. Hamilton-Fieldman
Special Master

[37] Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.